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COMMISSION IMPLEMENTING REGULATION (EU) 2024/2781

of 31 October 2024

amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 8-hydroxyquinoline, aminopyralid, azoxystrobin, *Candida oleophila* strain O, chlorantraniliprole, fluroxypyr, imazalil, kresoxim-methyl, metobromuron, oxyfluorfen, *Paecilomyces fumosoroseus* strain FE 9901, tefluthrin and terbuthylazine

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ([1]), and in particular Article 17, first paragraph, thereof,

Whereas:

(1) Commission Implementing Regulation (EU) No 993/2011 ([2]) approved the active substance 8-hydroxyquinoline until 31 December 2021. Commission Implementing Regulation (EU) No 891/2014 ([3]) approved the active substance aminopyralid until 31 December 2024. Commission Implementing Regulation (EU) No 703/2011 ([4]) approved the active substance azoxystrobin until 31 December 2021. Commission Implementing Regulation (EU) No 373/2013 ([5]) approved the active substance *Candida oleophila* strain O until 30 September 2023. Commission Implementing Regulation (EU) No 1199/2013 ([6]) approved the active substance chlorantraniliprole until 30 April 2024. Commission Implementing Regulation (EU) No 736/2011 ([7]) approved the active substance fluroxypyr until 31 December 2021. Commission Implementing Regulation (EU) No 705/2011 ([8]) approved the active substance

([1]) OJ L 309, 24.11.2009, p. 1, ELI: http://data.europa.eu/eli/reg/2009/1107/oj.

([2]) Commission Implementing Regulation (EU) No 993/2011 of 6 October 2011 approving the active substance 8-hydroxyquinoline, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 263, 7.10.2011, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2011/993/oj).

([3]) Commission Implementing Regulation (EU) No 891/2014 of 14 August 2014 approving the active substance aminopyralid, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 243, 15.8.2014, p. 47, ELI: http://data.europa.eu/eli/reg_impl/2014/891/oj).

([4]) Commission Implementing Regulation (EU) No 703/2011 of 20 July 2011 approving the active substance azoxystrobin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 190, 21.7.2011, p. 33, ELI: http://data.europa.eu/eli/reg_impl/2011/703/oj).

([5]) Commission Implementing Regulation (EU) No 373/2013 of 23 April 2013 approving the active substance Candida oleophila strain O, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 112, 24.4.2013, p. 10, ELI: http://data.europa.eu/eli/reg_impl/2013/373/oj).

([6]) Commission Implementing Regulation (EU) No 1199/2013 of 25 November 2013 approving the active substance chlorantraniliprole, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 315, 26.11.2013, p. 69, ELI: http://data.europa.eu/eli/reg_impl/2013/1199/oj).

([7]) Commission Implementing Regulation (EU) No 736/2011 of 26 July 2011 approving the active substance fluroxypyr, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 195, 27.7.2011, p. 37, ELI: http://data.europa.eu/eli/reg_impl/2011/736/oj).

([8]) Commission Implementing Regulation (EU) No 705/2011 of 20 July 2011 approving the active substance imazalil, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 190, 21.7.2011, p. 43, ELI: http://data.europa.eu/eli/reg_impl/2011/705/oj).

imazalil until 31 December 2021. Commission Implementing Regulation (EU) No 810/2011 ([9]) approved the active substance kresoxim-methyl until 31 December 2021. Commission Implementing Regulation (EU) No 890/2014 ([10]) approved the active substance metobromuron until 31 December 2024. Commission Implementing Regulation (EU) No 798/2011 ([11]) approved the active substance oxyfluorfen until 31 December 2021. Commission Implementing Regulation (EU) No 378/2013 ([12]) approved the active substance *Paecilomyces fumosoroseus* strain FE 9901 until 30 September 2023. Commission Implementing Regulation (EU) No 800/2011 ([13]) approved the active substance tefluthrin until 31 December 2021 and Commission Implementing Regulation (EU) No 820/2011 ([14]) approved the active substance terbuthylazine until 31 December 2021.

(2) The respective approvals of the active substances 8-hydroxyquinoline, aminopyralid, azoxystrobin, *Candida oleophila* strain O, chlorantraniliprole, fluroxypyr, imazalil, kresoxim-methyl, metobromuron, oxyfluorfen, *Paecilomyces fumosoroseus* strain FE 9901, tefluthrin and terbuthylazine are included in Part B of the Annex to Commission Implementing Regulation (EU) No 540/2011 ([15]).

(3) Commission Implementing Regulation (EU) 2023/2592 ([16]) extended the approval period of the active substance 8-hydroxyquinoline until 31 December 2024.

(4) Commission Implementing Regulation (EU) 2019/291 ([17]) extended the respective approval periods of the active substances azoxystrobin, fluroxypyr, imazalil, kresoxim-methyl, oxyfluorfen, tefluthrin and terbuthylazine until 31 December 2024.

([9]) Commission Implementing Regulation (EU) No 810/2011 of 11 August 2011 approving the active substance kresoxim-methyl, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 207, 12.8.2011, p. 7, ELI: http://data.europa.eu/eli/reg_impl/2011/810/oj).

([10]) Commission Implementing Regulation (EU) No 890/2014 of 14 August 2014 approving the active substance metobromuron, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 243, 15.8.2014, p. 42, ELI: http://data.europa.eu/eli/reg_impl/2014/890/oj).

([11]) Commission Implementing Regulation (EU) No 798/2011 of 9 August 2011 approving the active substance oxyfluorfen, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 and Commission Decision 2008/934/EC (OJ L 205, 10.8.2011, p. 9, ELI: http://data.europa.eu/eli/reg_impl/2011/798/oj).

([12]) Commission Implementing Regulation (EU) No 378/2013 of 24 April 2013 approving the active substance Paecilomyces fumosoroseus strain FE 9901, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 113, 25.4.2013, p. 5, ELI: http://data.europa.eu/eli/reg_impl/2013/378/oj).

([13]) Commission Implementing Regulation (EU) No 800/2011 of 9 August 2011 approving the active substance tefluthrin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 and amending Commission Decision 2008/934/EC (OJ L 205, 10.8.2011, p. 22, ELI: http://data.europa.eu/eli/reg_impl/2011/800/oj).

([14]) Commission Implementing Regulation (EU) No 820/2011 of 16 August 2011 approving the active substance terbuthylazine, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 and Commission Decision 2008/934/EC (OJ L 209, 17.8.2011, p. 18, ELI: http://data.europa.eu/eli/reg_impl/2011/820/oj).

([15]) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2011/540/oj).

([16]) Commission Implementing Regulation (EU) 2023/2592 of 21 November 2023 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-naphthylacetamide, 1-naphthylacetic acid, 2-phenylphenol (incl. its salts such as sodium salt), 8-hydroxyquinoline, amidosulfuron, bifenox, dicamba, difenoconazole, diflufenican, dimethachlor, esfenvalerate, etofenprox, fenoxaprop-P, fenpropidin, fenpyrazamine, fluazifop P, lenacil, napropamide, nicosulfuron, paraffin oils, paraffin oil, penconazole, picloram, prohexadione, spiroxamine, sulphur, tetraconazole and tri-allate (OJ L, 2023/2592, 22.11.2023, ELI: http://data.europa.eu/eli/reg_impl/2023/2592/oj).

([17]) Commission Implementing Regulation (EU) 2019/291 of 19 February 2019 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-naphthylacetamide, 1-naphthylacetic acid, acrinathrin, azoxystrobin, fluazifop p, fluroxypyr, imazalil, kresoxim-methyl, oxyfluorfen, prochloraz, prohexadione, spiroxamine, tefluthrin and terbuthylazine (OJ L 48, 20.2.2019, p. 17, ELI: http://data.europa.eu/eli/reg_impl/2019/291/oj).

(5) Commission Implementing Regulation (EU) 2020/2007 ([18]) extended the respective approval periods of the active substances *Candida oleophila* strain O, chlorantraniliprole and *Paecilomyces fumosoroseus* strain FE 9901 until 31 December 2024.

(6) Applications and supplementary dossiers for the renewal of the approvals of each of these active substances were submitted in accordance with Commission Implementing Regulation (EU) 2020/1740 ([19]). On 16 August 2019, 23 May 2022, 28 January 2019, 15 March 2022, 29 July 2022, 30 March 2022, 31 May 2022, 11 October 2023, 10 August 2022, 10 August 2022 and 27 July 2022 respectively, the rapporteur Member States for 8-hydroxyquinoline, aminopyralid, azoxystrobin, *Candida oleophila* strain O, chlorantraniliprole, fluroxypyr, kresoxim-methyl, metobromuron, oxyfluorfen, *Paecilomyces fumosoroseus* strain FE 9901 and terbuthylazine informed the co-rapporteur Member States, the Commission and the European Food Safety Authority (the 'Authority') that they had assessed the admissibility, in particular the completeness and the timeliness, of each of these applications, and concluded that they were admissible. The supplementary dossiers for the renewal of the approval of imazalil and tefluthrin were submitted via the central submission system on 16 December 2021 and 17 February 2022, respectively and the rapporteur Member States are assessing the admissibility of the applications

(7) For the active substances aminopyralid, azoxystrobin, *Candida oleophila* strain O, chlorantraniliprole, imazalil, kresoxim-methyl, metobromuron, oxyfluorfen, *Paecilomyces fumosoroseus* strain FE 9901, tefluthrin and terbuthylazine, the risk assessment pursuant to Article 11 of Implementing Regulation (EU) 2020/1740 has not yet been finalised by the respective rapporteur Member States and additional time is required to complete the remaining steps in each renewal procedure.

(8) For the active substance fluroxypyr, the Authority needs additional time to conclude the risk assessment carried out for the substance, including, where appropriate, a public consultation and a consultation of experts. Additional time is also necessary for the Commission to adopt the ensuing risk management decision.

(9) For the active substance 8-hydroxyquinoline, the Authority has communicated its conclusion to the applicant, the Member States and the Commission. The Commission has presented a renewal report and a draft Regulation on the renewal of this active substance's approval to the Standing Committee on Plants, Animals, Food and Feed. Additional time is necessary for the delivery of its opinion and for the Commission to adopt the ensuing risk management decision.

(10) It is therefore likely that no decision on the renewal of the approvals of those active substances can be taken before the expiry of their respective approval periods on 31 December 2024, and the reasons for the delays in the renewal procedures are beyond the control of the respective applicants. Therefore, the approval periods of those active substances should be extended in order to enable the completion of the assessments required and to finalise the respective procedures on renewal of approval.

([18]) Commission Implementing Regulation (EU) 2020/2007 of 8 December 2020 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-decanol, 1,4-dimethylnaphthalene, 6-benzyladenine, acequinocyl, Adoxophyes orana granulovirus, aluminium sulfate, amisulbrom, Aureobasidium pullulans (strains DSM 14940 and DSM 14941), azadirachtin, Bacillus pumilus QST 2808, benalaxyl-M, bixafen, bupirimate, Candida oleophila strain O, chlorantraniliprole, disodium phosphonate, dithianon, dodine, emamectin, flubendiamide, fluometuron, fluxapyroxad, flutriafol, hexythiazox, imazamox, ipconazole, isoxaben, L-ascorbic acid, lime sulphur, orange oil, Paecilomyces fumosoroseus strain FE 9901, pendimethalin, penflufen, penthiopyrad, potassium phosphonates, prosulfuron, Pseudomonas sp. strain DSMZ 13134, pyridalyl, pyriofenone, pyroxsulam, quinmerac, S-abscisic acid, sedaxane, sintofen, sodium silver thiosulfate, spinetoram, spirotetramat, Streptomyces lydicus strain WYEC 108, tau-fluvalinate, tebufenozide, tembotrione, thiencarbazone, valifenalate, zinc phosphide (OJ L 414, 9.12.2020, p. 10, ELI: http://data.europa.eu/eli/reg_impl/2020/2007/oj).

([19]) Commission Implementing Regulation (EU) 2020/1740 of 20 November 2020 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and repealing Commission Implementing Regulation (EU) No 844/2012 (OJ L 392, 23.11.2020, p. 20, ELI: http://data.europa.eu/eli/reg_impl/2020/1740/oj).

(11) For the active substances aminopyralid, azoxystrobin, *Candida oleophila* strain O, chlorantraniliprole, imazalil, kresoxim-methyl, metobromuron, oxyfluorfen, *Paecilomyces fumosoroseus* strain FE 9901, tefluthrin and terbuthylazine, as the risk assessment has not yet been finalised by the respective rapporteur Member States and in light of the time required to complete the remaining steps in each renewal procedure, the duration of the extension of the approval periods should be set at 29 months.

(12) For the active substance fluroxypyr, as the Authority needs additional time to reach a conclusion on the risk assessment after the two additional months necessary to finalise the public consultation pursuant to Article 12 of Implementing Regulation (EU) 2020/1740, and in light of the time required to complete the remaining steps in the renewal procedure, the extension of the approval period for this active substance should be set at 25 months and 2 weeks.

(13) For the active substance 8-hydroxyquinoline, as the delivery of an opinion of the Standing Committee on Plants, Animals, Food and Feed is pending, and in light of the time required to complete the remaining steps in the renewal procedure, the duration of the extension of the approval period for this active substance should be set at 12 months.

(14) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(15) In case the Commission adopts a Regulation providing that the approval of an active substance referred to in the Annex to this Regulation is not renewed, the Commission will set the expiry date at the date of entry into force of that Regulation or at the same date as it stood before the adoption of this Regulation, whichever date is later. In case the Commission adopts a Regulation providing for the renewal of the approval of an active substance referred to in the Annex to this Regulation, the Commission will set the earliest possible application date, as appropriate under the circumstances.

(16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 31 October 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Part B of the Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in the sixth column, expiration of approval, of row 4, Azoxystrobin, the date is replaced by '31 May 2027';

(2) in the sixth column, expiration of approval, of row 5, Imazalil, the date is replaced by '31 May 2027';

(3) in the sixth column, expiration of approval, of row 8, Kresoxim-methyl, the date is replaced by '31 May 2027';

(4) in the sixth column, expiration of approval, of row 9, Fluroxypyr, the date is replaced by '15 February 2027';

(5) in the sixth column, expiration of approval, of row 10, Tefluthrin, the date is replaced by '31 May 2027';

(6) in the sixth column, expiration of approval, of row 11, Oxyfluorfen, the date is replaced by '31 May 2027';

(7) in the sixth column, expiration of approval, of row 16, Terbuthylazine, the date is replaced by '31 May 2027';

(8) in the sixth column, expiration of approval, of row 18, 8-hydroxyquinoline, the date is replaced by '31 December 2025';

(9) in the sixth column, expiration of approval, of row 37, *Candida oleophila* strain O, the date is replaced by '31 May 2027';

(10) in the sixth column, expiration of approval, of row 39, *Paecilomyces fumosoroseus* strain FE 9901, the date is replaced by '31 May 2027';

(11) in the sixth column, expiration of approval, of row 62, Chlorantraniliprole, the date is replaced by '31 May 2027';

(12) in the sixth column, expiration of approval, of row 76, Metobromuron, the date is replaced by '31 May 2027';

(13) in the sixth column, expiration of approval, of row 77, Aminopyralid, the date is replaced by '31 May 2027'.